

Notice of Allowability

Application No.

10/019,743

Examiner

Anand U. Desai, Ph.D.

Applicant(s)

SASAKI ET AL.

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to December 1, 2005.
2. ☒ The allowed claim(s) is/are 1-15, and 18.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on December 1, 2005 has been entered.

EXAMINER'S AMENDMENT

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Dr. Jonathan M. Sparks on February 3, 2006.

Examiner's Amendment to the Claims:

1. (Currently Amended) A process for preparing a purified LH-RH derivative which comprises the steps of:

contacting a solution containing the LH-RH derivative with a methacrylic synthetic adsorption resin; and contacting the solution containing the LH-RH derivative with an aromatic synthetic adsorption resin, thereby preparing a purified LH-RH derivative.

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6. (Currently Amended) The process according to claim 5, wherein an average particle size of the styrene-divinylbenzene, synthetic adsorption resin is about 60 μm ~~pm~~ to about 150 μm ~~pm~~.

7. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with a methacrylic synthetic adsorption resin below about 10°C.

8. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with an aromatic synthetic adsorption resin at about 10°C to about 20°C.

9. (Currently Amended) The process according to claim 1, wherein said process comprises subjecting a solution containing the LH-RH derivative ~~to the step for treatment~~ with a methacrylic, synthetic adsorption resin, followed by subjecting ~~to the step for treatment~~ the LH-RH derivative solution with an aromatic, synthetic adsorption resin.

10. (Currently Amended) The process according to claim 1, said process comprises passing a solution containing the LH-RH derivative through ~~a resin~~ the methacrylic synthetic adsorption resin in the step of contacting the LH-RH derivative ~~with the methacrylic synthetic adsorption resin~~; and then eluting the LH-RH derivative, which is adsorbed on the resin, with an aqueous solution of acetic acid.

12. (Currently Amended) The process according to claim 1, wherein said process comprises passing a solution containing the LH-RH derivative through ~~a resin~~ the methacrylic, synthetic adsorption resin in the step of contacting the LH-RH derivative ~~with a methacrylic,~~

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~~synthetic adsorption resin~~, followed by washing with an aqueous solution of ethanol, and then by eluting the LH-RH derivative that is adsorbed on the resin.

13. (Currently Amended) The process according to claim 1, wherein a solution containing the LH-RH derivative is ~~that~~ obtained by subjecting the LH-RH derivative protected with protective group(s) to a deprotection reaction followed by a neutralization reaction below about 10°C.

14. (Currently Amended) The process according to claim 1, wherein a solution containing the LH-RH derivative is ~~that~~ obtained by subjecting the LH-RH derivative protected with protected group(s) to a deprotection reaction and then a neutralization reaction below about 10°C, followed by subjecting the resulting mixture to extraction of the LH-RH derivative and then concentration of the extract below 25°C.

Allowable Subject Matter

3. Claims 1-15, and 18 are allowable.

The following is an examiner's statement of reasons for allowance: The prior art of record does not teach a process for preparing a purified LH-RH derivative which comprises the steps of contacting a solution containing the LH-RH derivative with a methacrylic synthetic adsorption resin; and contacting the solution containing the LH-RH derivative with an aromatic synthetic adsorption resin, thereby preparing a purified LH-RH derivative. Hatanaka et al. (U.S. 6,211,333 B1) describes the method of producing leuporelin, but does not describe the use of a methacrylic synthetic adsorption resin and an aromatic adsorption resins as is currently being claimed.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 2, 2006



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER